K000209

AUG 1 8 2000

I. 510(k) SUMMARY

[Refer to 21 CFR §807.92]

Submitted by:	Wellhofer North America (WNA) 3111 Stage Post Dr., Suite 105 Bartlett, TN 38133, USA Phone: 901-386-2242 FAX: 901-382-9453
Contact Person:	Chuck Lindley (WNA)
Date Prepared:	1999-27-12
Proprietary Name:	Dose 1 Dosimeter
Common Name:	Reference Class Therapy Dosimeter
Classification Name:	Class II 21 §CFR 892.5050 Advanced Therapy Dosimeter Model 35040
Predicate Device:	Keithley Instruments, Inc 28775 Aurora Road Cleveland, OH 44139 510(k) Document Control Number K942083

Description of the Device:

The Dose 1 Dosimeter is a reference grade single channel electrometer designed to precisely measure charge, current, dose, dose rate and dose per monitor unit in radiation fields within the therapeutic energy ranges. It consists of the measuring device, a parameter definition and administration software, an extension cable and a communication cable. It can be used with suitable ionization chambers and solid state detectors.

Intended Use of the Device:

The Dose 1 Therapy Dosimeter is designed for calibration dosimetry of therapeutic radiation treatment machines including high energy accelerators, ^{60}Co, and brachytherapy equipment. It can be used for clinical routine checks, calibration, compliance testing, installation and set-up of new equipment, and trouble-shooting. It **must not be used** in contact with patient.

Technological Characteristics:

- The indications for use of the Dose 1 are exactly the same as the predicate device.
- The design is essentially the same as in the predicate device.
- The manufacturing and testing, process and procedures are the same.
- The materials used are the same as the predicate device.
- The specifications are the same as the predicate devices.
- The indications for use, design, materials, manufacturing, and specifications of the Dose 1 do not raise any issues with regard to safety and effectiveness.
- Wellhofer considers the Dose 1 equivalent in all respects to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2000

Chuck Lindley
Vice President
Scanditronix Wellhöfer North America, Inc.
3111 Stage Post Drive, Suite 105
Bartlett, TN 38133

Re: K000209
Dose 1 Dosimeter (Reference Class Therapy Dosimeter)
Dated: May 25, 2000
Received: May 26, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Lindley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

II. INDICATIONS FOR USE STATEMENT

510(k) Number: (not known)

Device Name: Dose 1 Therapy Dosimeter

Indications For Use: The Dose 1 Therapy Dosimeter is designed for calibration dosimetry of therapeutic radiation treatment machines including high energy accelerators, ^{60}Co, and brachytherapy equipment. It can be used for clinical routine checks, calibration, compliance testing, installation and set-up of new equipment, and trouble-shooting. It **must not be used** in contact with patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ *(Per 21 CFR §801.109)*

Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000209/S001